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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/464,426	12/16/1999	CARLOS O. STALGIS	IN0964Q	7516

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER	
FOLEY, SHANON A	
ART UNIT	PAPER NUMBER
1648	14

DATE MAILED: 07/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/464,426	STALGIS ET AL.	
	Examiner	Art Unit	
	Shanon Foley	1648	

-- The MAILING DATE of this communication appears on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 5/10/2 .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-9 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-9 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Prosecution Application

The request filed on 5/10/2 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/464426 is acceptable and a CPA has been established. An action on the CPA follows.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is drawn to a method of treating chronic hepatitis C patients by administering a therapeutically effective "induction" dosing amount of pegylated interferon alpha and ribavirin for a first time period and administering a therapeutically effective amount of the compounds for a second time period. It cannot be determined what is intended to be "induced" by the compounds in the first treatment period and that is not induced in the second treatment period. Further, although the claim appears to presume distinction between the amount of pegylated interferon in the first and second time periods, the length of each time period is unclear. Is there a discontinuation of administering the compounds between treatment periods? There does not appear to be any sort of demarcation between treatment periods that would allow one to realize when the first treatment period has ended and the second has begun, except for an arbitrary decrease in the amount of pegylated interferon administered. The relative amounts of pegylated

interferon administered cannot be determined because the claim does not indicate any amount of the substance to be administered. "More than" is a relative phrase and does not add meaning to the claim since "more than" can be one picogram more. It is also unclear what is intended by a "substantially lower" the amount of detectable HCV-RNA after the first treatment period. Since there is nothing in the claim comparing amounts of HCV-RNA, it cannot be determined what a "substantially lower" amount is relative to. At the end of the second treatment period, HCV-RNA is to be undetectable. If the amount of HCV-RNA is undetectable after the first treatment period, it is presumed that the undetectable amount would be "substantially lower" than the amount the patient had before treatment started. Therefore, "substantially lower" does not add breadth or meaning to the claim. This rejection affects all claims 2-9.

Claims 2, 3, 5, 8, and 9 are drawn to administering a certain amount of ribavirin in the first and/or second time periods. Since there is no distinction between the treatment periods of claim 1, the amount of ribavirin administered during the first and the second is unclear.

Claim Rejections - 35 USC § 102

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Albrecht (US 6,172,046).

The claims are drawn to a method of treating chronic hepatitis C (HCV) serotypes 1, 2, and/or 3 infections by administering about 400 to about 1600 mg per day of ribavirin a therapeutically effective amount of pegylated alpha interferon for a time period of about 40 to about 50 weeks to eradicate detectable HCV-RNA for at least 24 weeks after the treatment period.

The claims also indicate that there are two treatment periods within the 40 to 50 week treatment regiment and that the amount of pegylated interferon administered in the first treatment period is "more than" the amount administered in the second treatment period. However, as explained above, these limitations are unclear and indefinite because there is no indication for how long each treatment period lasts and there is no distinction between the end of one treatment period and the beginning of another. In addition, the relative amount of pegylated interferon which is determined to be "more than" that administered in the second treatment period does not add a meaningful limitation that can be searched because it cannot be determined what would be considered "more than" an undefined amount.

Albrecht teaches a method of treating chronic HCV patients by administering about 400 to about 1200 mg per day of ribavirin and about 20 to about 250 micrograms or 0.5 to 2.0 micrograms per kilogram of pegylated interferon alpha per kilogram on a weekly, twice weekly, four times a week, or on a daily basis for 40 to 50 weeks to eradicate detectable amounts of HCV-RNA for at least 24 weeks after the treatment period. See column 1, line 64 to column 2, line 9, column 3, lines 31-42, and claims 1-4 and 10.

Although Albrecht does not specifically teach treating HCV genotypes 2 or 3, the patent teaches results of treatments of patients in Tables 4 and 8 to impart information about patients

"with genotype[s] other than 1", see column 10, lines 34-39. Therefore, the "other" genotypes would encompass information regarding treatment of patients with "other" genotypes such as 2 and 3.

Albrecht also does not specifically teach altering the amount of pegylated interferon during a treatment period. However, the patent teaches that the amount of pegylated interferon administered ranges between about 20 to about 250 micrograms or 0.5 to 2.0 micrograms per kilogram on a weekly, twice weekly, four times a week, or on a daily basis. Therefore, the patent claims (claim 10 to be specific) anticipate administering any amount of pegylated interferon within the recited range for any of the frequencies listed. Alternatively, one of ordinary skill in the art at the time the invention was made would have been motivated to choose between the dosage amounts and frequencies recited in the patent claims depending on the type of hepatitis to be treated or to enhance the response of a patient to the therapy. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation for producing the claimed invention because it is routine in the medical arts to optimize dosage amounts of a substance for each individual patient and/or severity of disease. Therefore, the teachings of Albrecht render the invention obvious if not anticipated.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley/SAF
July 25, 2002

JAMES HOUSEL 7/29/02
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600